



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/381,055 | 10/30/2000 | Aziz Asghar | 1103326-0590 | 3456 |

7590

03/11/2005

White & Case
Patent Department
1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/381,055

Applicant(s)

ASGHAR ET AL

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-19 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Pursuant to a second preliminary amendment (filed 2/25/05), claims 1-8 have been cancelled, claims 9 and 12 amended, and claims 13-19 added. Claims 9-19 are now pending.

Applicants' election of Group II (claims 10-12) is acknowledged, as is the elected specie. The elected specie is remacemide, the chemical name of which is 2-amino-N-(1-methyl-1,2-diphenylethyl)acetamide, and the Chem. Abstracts Registry number for which is 111686-79-4. This compound falls within the scope of formula I when the substituent variables are as follows:

R^1 = phenyl

R^2 = phenyl

R^3 = methyl

R^4 = hydrogen

Applicants have traversed the restriction requirement by arguing that PCT rules confer "immunity" from the same. However, the elected invention (claims 10-12) does not "define a contribution" over the prior art. As it happens, at the time of the invention, there were a vast number of references that disclosed NMDA receptor antagonists. Perhaps it is true that claim 9 is novel, and perhaps not. But claim 10 would not have been novel even 20 years ago; the "intended use" limitation (treatment of IBS) does not change this analysis.

Further, not only does claim 10 fail to “define a contribution” over the prior art, claim 12 is also not novel as of the priority date of the application. Consider the following passage from the MPEP (section 1850):

PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By “dependent” claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression “category of claim” referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

Accordingly, “unity of invention” is lacking, and the restriction is still deemed to be proper. Notwithstanding the foregoing, applicants may change their

election to that of Group I (now claims 9 and 13-19) if the request to change the election is made in response to this Office action. Any such request made after the second Office action (on the merits) will be denied. In the event that such a request is made, the species election (remacemide) will remain in force.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Griffith (USP 5,331,007).

Griffith discloses (col 1, line 35+) compounds which can be used for treatment of neurological disorders. Also disclosed (col 4, line 43+) is pharmaceutical compositions. Griffith does not disclose that the compounds can be used to treat IBS, but this property is inherent.

Thus, the claims are anticipated.



The following is a quotation of 35 USC. §103 which forms the basis for all

obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 10-12 rejected under 35 U.S.C. §103 as being unpatentable over Griffith (EP 279,937).

Griffith discloses compounds falling with the scope of instant claim 12. Griffith discloses that the compounds are pharmacologically active, but appears not to recite the term "pharmaceutical composition". However, the drug formulation specialist of ordinary skill is aware of how to prepare pharmaceutical compositions.

Thus, the claims are anticipated.



WO 93/22279 was stricken from the IDS because of the absence of a translation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1400